

Amendments to the Claims:

1-28 (Canceled)

21 29. (Currently amended) A composition having a pH of about pH 5.5 or greater, wherein said composition comprises:

(a) biologically active insulin-like growth factor-1 (IGF-I) or biologically active analogue thereof having an amino acid sequence that shares at least 70% sequence identity with the amino acid sequence for human IGF-I, wherein said IGF-I or analogue thereof is present at a concentration of about 12 mg/ml ~~or greater~~ to about 200 mg/ml when said composition is at a temperature of about 4°C; and

(b) a solubilizing compound comprising a guanidinium group, wherein said solubilizing compound is present in said composition in an amount sufficient to make said IGF-I or analogue thereof soluble at a concentration of about 12 mg/ml ~~or greater~~ to about 200 mg/ml when said composition is at a temperature of about 4°C.

30. (Previously added) The composition of claim 29, wherein said solubilizing compound is guanidine hydrochloride.

31. (Previously amended) The composition of claim 29, wherein said solubilizing compound is selected from the group consisting of arginine, N-acetyl-arginine, a dipeptide containing arginine, and a tripeptide containing arginine, wherein said dipeptide or said tripeptide increases solubility of said IGF-I or analogue thereof at a pH of about pH 5.5 or greater.

32. (Previously added) The composition of claim 31, wherein said solubilizing compound is arginine.

33. (Previously added) The composition of claim 32, wherein said IGF-I or analogue thereof has an amino acid sequence having at least 95% sequence identity with the amino acid sequence for human IGF-I.

34. (Previously added) The composition of claim 32, wherein said IGF-I is human IGF-I.

35. (Previously added) The composition of claim 34, wherein said arginine is present in a molar concentration range from about 10 mM to about 1 M.

36. (Previously added) The composition of claim 35, wherein said arginine is present in a molar concentration range from about 15 mM to about 500 mM.

37. (Previously added) The composition of claim 36, wherein said arginine is present in a molar concentration range from about 20 mM to about 200 mM.

38. (Previously added) The composition of claim 34, wherein said pH is in a range from about pH 5.5 to about pH 9.0.

39. (Previously added) The composition of claim 38, wherein said pH is in a range from about pH 5.7 to about pH 6.3.

40. (Previously added) The composition of claim 39, wherein said pH is about pH 6.0.

42 41. (Currently amended) The composition of claim 34, wherein said IGF-I is present in said composition at a concentration of about ~~12~~ 15 mg/ml to about 200 mg/ml.

42. (Currently amended) The composition of claim 41, wherein said IGF-I is present in said composition at a concentration of about ~~15~~ 20 mg/ml to about 200 mg/ml.

43. (Previously added) The composition of claim 42, wherein said IGF-I is present in said composition at a concentration of about 25 mg/ml to about 200 mg/ml.

44. (Previously added) The composition of claim 29, wherein said composition comprises sodium chloride at a molar concentration of about 150 mM.

45. (Previously added) The composition of claim 29 comprising a buffer selected from the group consisting of a glutaric acid buffer, a maleic acid buffer, a succinic acid buffer, a citric acid buffer, imidazole, and a histidine buffer.

46. (Currently amended) A composition comprising:

13 (a) biologically active insulin-like growth factor-1 (IGF-I) or biologically active analogue thereof having an amino acid sequence that shares at least 70% sequence identity with the amino acid sequence for human IGF-I, wherein said IGF-I or analogue thereof is present at a concentration of about 12 mg/ml ~~or greater~~ to about 200 mg/ml when said composition is at a temperature of about 4°C;

(b) a solubilizing compound selected from the group consisting of arginine, N-acetyl-arginine, a dipeptide containing arginine, a tripeptide containing arginine, and guanidine hydrochloride, wherein said dipeptide or said tripeptide increases solubility of said IGF-I or analogue thereof at a pH of about pH 5.5 ~~or greater~~, and wherein said solubilizing compound is present in said composition in an amount sufficient to make said IGF-I or analogue thereof soluble at a concentration of about 12 mg/ml to about 200 mg/ml when said composition is at a temperature of about 4°C; and

(c) a buffer such that the composition has a pH of about pH 5.5 to about pH 9.0.

47. (Previously added) The composition of claim 46, wherein said IGF-I or analogue thereof has an amino acid sequence having at least 95% sequence identity with the amino acid sequence for human IGF-I.

48. (Previously added) The composition of claim 46, further comprising sodium chloride at a molar concentration of about 150 mM.

49-84 (Canceled)

34 85. (Currently amended) A composition having a pH of about pH 5.5 or greater, wherein said composition comprises:

(a) biologically active human insulin-like growth factor-1 (IGF-I), wherein said IGF-I is present at a concentration of about 12 mg/ml ~~or greater~~ to about 200 mg/ml when said composition is at a temperature of about 4°C; and

(b) a solubilizing compound comprising a guanidinium group, wherein said solubilizing compound is present in said composition in an amount sufficient to make said IGF-I soluble at a concentration of about 12 mg/ml ~~or greater~~ to about 200 mg/ml when said composition is at a temperature of about 4°C.

86. (Previously added) The composition of claim 85, wherein said solubilizing compound is guanidine hydrochloride.

87. (Previously added) The composition of claim 85, wherein said solubilizing compound is arginine.

88. (Previously added) The composition of claim 87, wherein said arginine is present in a molar concentration range from about 10 mM to about 1 M.

89. (Previously added) The composition of claim 88, wherein said arginine is present in a molar concentration range from about 15 mM to about 500 mM.

90. (Previously added) The composition of claim 89, wherein said arginine is present in a molar concentration range from about 20 mM to about 200 mM.

91. (Previously added) The composition of claim 87, wherein said pH is in a range from about pH 5.5 to about pH 9.0.

92. (Previously added) The composition of claim 91, wherein said pH is in a range from about pH 5.7 to about pH 6.3.

93. (Previously added) The composition of claim 92, wherein said pH is about pH 6.0.

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94. (Currently amended) The composition of claim 87, wherein said IGF-I is present in said composition at a concentration of about ~~12~~ 15 mg/ml to about 200 mg/ml.

95. (Currently amended) The composition of claim 94, wherein said IGF-I is present in said composition at a concentration of about ~~15~~ 20 mg/ml to about 200 mg/ml.

96. (Previously added) The composition of claim 95, wherein said IGF-I is present in said composition at a concentration of about 25 mg/ml to about 200 mg/ml.

97. (Previously added) The composition of claim 85, wherein said composition comprises sodium chloride at a molar concentration of about 150 mM.

98. (Previously added) The composition of claim 85 comprising a buffer selected from the group consisting of a glutaric acid buffer, a maleic acid buffer, a succinic acid buffer, a citric acid buffer, imidazole, and a histidine buffer.

99. (Currently amended) A composition comprising:

- 36
- (a) biologically active human insulin-like growth factor-1 (IGF-I), wherein said IGF-I is present at a concentration of about 12 mg/ml ~~or greater~~ to about 200 mg/ml when said composition is at a temperature of about 4°C;
 - (b) a solubilizing compound selected from the group consisting of arginine and guanidine hydrochloride, wherein said solubilizing compound is present in said composition in an amount sufficient to make said IGF-I or analogue thereof soluble at a concentration of about 12 mg/ml to about 200 mg/ml when said composition is at a temperature of about 4°C; and
 - (c) a buffer such that the composition has a pH of about pH 5.5 to about pH 9.0.
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100. (Previously added) The composition of claim 99, further comprising sodium chloride at a molar concentration of about 150 mM.

101. (Currently amended) A composition having a pH of about pH 5.5 or greater, wherein said composition comprises:

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- (a) biologically active human insulin-like growth factor-1 (IGF-I), wherein said IGF-I is present at a concentration of about 12 mg/ml ~~or greater~~ to about 200 mg/ml when said composition is at a temperature of about 4°C; and
 - (b) arginine in an amount sufficient to make said IGF-I soluble at a concentration of about 12 mg/ml ~~or greater~~ to about 200 mg/ml when said composition is at a temperature of about 4°C.
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102. (Previously added) The composition of claim 101, wherein said arginine is present in a molar concentration range from about 10 mM to about 1 M.


103. (Previously added) The composition of claim 102, wherein said arginine is present in a molar concentration range from about 15 mM to about 500 mM.

104. (Previously added) The composition of claim 103, wherein said arginine is present in a molar concentration range from about 20 mM to about 200 mM.

105. (Previously added) The composition of claim 101, wherein said pH is in a range from about pH 5.5 to about pH 9.0.

106. (Previously added) The composition of claim 105, wherein said pH is in a range from about pH 5.7 to about pH 6.3.

107. (Previously added) The composition of claim 106, wherein said pH is about pH 6.0.

 108. (Currently amended) The composition of claim 101, wherein said IGF-I is present in said composition at a concentration of about ~~12~~ 15 mg/ml to about 200 mg/ml.

109. (Currently amended) The composition of claim 108, wherein said IGF-I is present in said composition at a concentration of about ~~15~~ 20 mg/ml to about 200 mg/ml.

110. (Previously added) The composition of claim 109, wherein said IGF-I is present in said composition at a concentration of about 25 mg/ml to about 200 mg/ml.

111. (Previously added) The composition of claim 101, wherein said composition comprises sodium chloride at a molar concentration of about 150 mM.

112. (Previously added) The composition of claim 101 comprising a buffer selected from the group consisting of a glutaric acid buffer, a maleic acid buffer, a succinic acid buffer, a citric acid buffer, imidazole, and a histidine buffer.